IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., BIOVAIL LABORATORIES INTERNATIONAL SRL, and ORTHO-MCNEIL, INC.,	)	
Plaintiffs/Counterclaim Defendants,	)	
v.	)	C.A. No. 07-255 (JJF) (CONSOLIDATED)
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	)	
Defendants/Counterclaim Plaintiffs.	)	

PLAINTIFFS' REPLY TO THE COUNTERCLAIMS SET FORTH IN DEFENDANTS' SECOND AMENDED ANSWER AND COUNTERCLAIMS

Plaintiffs/counterclaim defendants Purdue Pharma Products L.P., Napp Pharmaceutical Group Ltd., Biovail Laboratories International, SRL, and Ortho-McNeil, Inc. (collectively, "Plaintiffs") reply to Defendants/counterclaim plaintiffs Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.'s (collectively, "Par") Counterclaims as follows:

REPLY

1. Admitted on information and belief.

2. Admitted on information and belief.

3. Admitted.

4. Admitted.

5. Admitted.

6. Admitted.

7. Par purports to assert claims arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202,

and purports to seek declaratory relief. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 7.

8. Par purports to base subject matter jurisdiction on the statutes listed in Paragraph 8. Plaintiffs do not contest that subject matter jurisdiction exists. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 8.

9. Admitted.

10. Since May 4, 2007, Purdue Pharma Products L.P. ("Purdue") and Napp Pharmaceutical Group Ltd. ("Napp") have been the assignees of U.S. Patent No. 6,254,887 (the "'887 patent"). Except as expressly admitted, Plaintiffs deny the averments of Paragraph 10.

11. Controlled release oral dosage formulations of tramadol are described in the '887 patent. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 11.

12. Admitted.

13. Since May 4, 2007, Purdue and Napp have been the assignees of U.S. Patent No. 7,074,430 ("the '430 patent"). Except as expressly admitted, Plaintiffs deny the averments of Paragraph 13.

14. Controlled release oral dosage formulations of tramadol are described in the '430 patent. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 14.

15. Admitted on information and belief.

REPLY TO FIRST COUNT

16. Plaintiffs repeat and incorporate their reply to Paragraphs 1-15.

17. Denied.

18. Admitted.

19. Admitted.

20. Denied.

REPLY TO SECOND COUNT

21. Plaintiffs repeat and incorporate their reply to Paragraphs 1-20.

22. Denied.

23. Admitted.

24. Admitted.

25. Denied.

REPLY TO THIRD COUNT

26. Denied.

27. Admitted.

28. Denied.

29. Purdue and Napp deny. Biovail Laboratories International, SRL, ("Biovail") and Ortho-McNeil, Inc. ("OMI") deny on information and belief.

30. Admitted.

31. Controlled release dosage formulations of tramadol are described in the '887 patent and in U.S. Patent No. 5,591,452 (the "'452 patent"). Except as expressly admitted, Plaintiffs deny the averments of Paragraph 31.

32. Admitted.

33. Tramadol is an opioid analgesic, which can be administered orally. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 33.

34. Admitted.

35. Since May 4, 2007, Purdue Pharma Products L.P. and Napp Pharmaceutical Group Ltd. have been the assignees of the '887 patent and the '452 patent. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 35.

36. The ‘887 and ‘452 patents were licensed to Ortho-McNeil, Inc. by Purdue Pharma Products L.P.

37. Admitted.

38. PriCara is a Division of Ortho McNeil-Janssen Pharmaceuticals, and markets Ultram® ER. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 38.

39. Admitted.

40. Admitted.

41. Admitted.

42. Mr. Davidson was an attorney of record for the ‘129 application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 42.

43. Brian M. Burn was the primary examiner for the ‘129 application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 43.

44. Admitted.

45. Admitted.

46. Admitted.

47. In the German ‘525 priority application, in vitro dissolution rate ranges stated for the controlled release preparations, when measured by USP Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm, are between 5 and 50% (by weight) tramadol released after 1 hour, between 10 and 75% (by weight) tramadol released after 2 hours, between 20 and 95% (by weight) tramadol released after 4 hours, between 40 and 100% (by weight) tramadol released after 8 hours, more than 50% (by weight) tramadol released after 12 hours, more than 70% (by weight) tramadol released after 18 hours and more

than 80% (by weight) tramadol released after 24 hours. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 47.

48. Sustained release compositions are disclosed in British Patent Application No. 9324045 ("the British '045 priority application"). Except as expressly admitted, Plaintiffs deny the averments of Paragraph 48.

49. Admitted.

50. Admitted.

51. In the British '544 priority application ("the British '544 priority application"), in vitro dissolution rate ranges stated for the controlled release preparations, when measured by Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm, are 0-50% tramadol released after 1 hour, 0-75% tramadol released after 2 hours, 3-95% tramadol released after 4 hours, 10-100% tramadol released after 8 hours, 20-100% tramadol released after 12 hours, 30-100% tramadol released after 16 hours, 50-100% tramadol released after 24 hours and more than 80% tramadol released after 36 hours. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 51.

52. British Patent Application No. 9404928 ("the British '928 priority application") states that it "relates generally to a method of manufacturing pharmaceutical dosage forms, for human or veterinary use, preferably sustained release particles, such particles having diameters ranging from 0.1 to 3.0 mm." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 52.

53. Examples 1-6 of the British '928 priority application contain Morphine Sulphate as the active ingredient. Examples 7-8 of the British '928 priority application contain

Tramadol Hydrochloride as the active ingredient. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 53.

54. Admitted.

55. On May 29, 1996, a letter on behalf of Grünenthal GmbH ("Grünenthal") was submitted to the European Patent Office in opposition to European Patent No. 624,366 ("the European '366 patent"). The European '366 patent is assigned to Euro-Celtique S.A. ("Euro-Celtique"). The '452 patent issued on January 7, 1997. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 55.

56. The European '366 patent was filed on April 29, 2004, claiming priority to the British '928 application, the British '045 priority application, the British '544 priority application, and the German '525 priority application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 56.

57. On information and belief based on statements made in the '887 prosecution history, the Grünenthal opposition letter asserted British Patent Application No. 2,196,848 (the British '848 application") against claims 5-7 of the European '366 patent to support Grünenthal's position that the subject matter is not based on an inventive step. The British '848 application is titled "Controlled release hydromorphone composition." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 57.

58. The British '848 application was filed October 22, 1987, listing priority data as GB 8626098, filed October 31, 1986. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 58.

59. Admitted.

60. The prosecution history of the ‘452 patent does not reflect the disclosure of Grünenthal’s opposition letter.

61. On information and belief, Plaintiffs deny the averments of Paragraph 61.

62. The ‘798 application was filed on July 10, 1996 as a divisional application of the ‘129 application. Euro-Celtique was named as the assignee for the ‘798 application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 62.

63. Admitted.

64. Admitted.

65. Mr. Davidson was an attorney of record for the ‘798 application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 65.

66. Examiner Brian M. Burn was one of the patent examiners whose name appears in the prosecution history of the ‘798 application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 66.

67. When filing the ‘798 application, the applicants wrote “[c]ancel in this application original claims 1-19 of the prior application (without prejudice) before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.).” On July 10, 1996, applicants filed a preliminary amendment stating “[p]lease cancel claims 1-41 without prejudice.” That preliminary amendment added new claims 42-65. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 67.

68. Admitted.

69. Admitted.

70. On October 27, 1998, Examiner Burn wrote: "[i]t is noted that Applicant has submitted an extremely large number of references for review." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 70.

71. Examiner Burn further wrote: "The courts have held that an applicant may be guilty of inequitable conduct if the applicant is aware that certain references within a large information disclosure statement are more material that [sic] the rest and does not inform the PTO as to which references the applicant considers to be most material." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 71.

72. Examiner Burn further wrote: "Thus, there has been an additional burden placed on applicants who submit large volumes of prior art to identify pieces of prior art which are deemed most material by the applicant." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 72.

73. Examiner Burn further wrote: "It is the examiner's intent, in raising this issue, to ensure that it is adequately addressed during ex parte proceedings and therefore could not become an issue after a patent is allowed." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 73.

74. Examiner Burn further wrote: "Therefore, it is suggested that Applicant, in their next correspondence with the PTO, identify those references they deem most material to the claimed invention." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 74.

75. Examiner Burn further wrote: "Applicant is also encouraged to review 37 C.F.R. § 1.56(b) wherein the standard for what constitutes a material reference is set forth and MPEP § 2004(13) which discusses the submission of long lists of clearly irrelevant and

marginally pertinent information." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 75.

76. Admitted.

77. Admitted.

78. In the March 1, 1999 response to the October 27, 1998 office action, applicants wrote: "In the Information Disclosure Statement filed on October 6, 1997, certain of Assignee's copending patent applications were brought to the Examiner's attention. The following is an updating and supplementation of that list: Applicants respectfully advise the Examiner of the following applications which are commonly assigned to the owners of the instant application." The Response describes six applications, then states: "Applicants also respectfully advise the Examiner of the following applications which were originally assigned to the owners of the instant application, but have since been assigned to an affiliated company," describing three more applications. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 78.

79. Admitted.

80. Admitted.

81. Paragraph 81 incorrectly identifies the '798 application as the "'789 application." Plaintiffs assume that references to the "'789 application" throughout Par's Counterclaims are actually to the '798 application. Except as denied, Plaintiffs admit the averments of Paragraph 81.

82. Admitted.

83. Admitted.

84. Admitted.

85. U.S. Patent No. 5,580,578 ("the '578 patent") states that it is "an object of the present invention to provide a controlled release formulation of a substrate comprising an active agent ... coated with an aqueous dispersion of a hydrophobic acrylic polymer such that there is a stable dissolution or other release profile of the active agent when placed in an environment of use, despite exposure to a variety of storage conditions, including accelerated storage conditions." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 85.

86. The '578 patent discloses fifteen (15) classes of active agents, one of which is "systemically active therapeutic agents," twenty-eight (28) classes of systemically active therapeutic agents, one of which is "opioids," and fourteen (14) different opioids, one of which is tramadol. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 86.

87. Admitted.

88. Admitted.

89. Mr. Davidson was an attorney of record for U.S. Patent Application Serial No. 08/097,558 ("the '558 application"). Except as expressly admitted, Plaintiffs deny the averments of Paragraph 89.

90. The primary examiner listed on the face of the '578 patent is Peter F. Kulkosky. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 90.

91. The '558 application was filed on July 27, 1993, and issued on December 3, 1996. The '798 application was filed on July 10, 1996, and issued on July 3, 2001. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 91.

92. The ‘798 application was filed on July 10, 1996. The ‘558 application issued as the ‘578 patent on December 3, 1996. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 92.

93. Admitted.

94. Dependent claim 47 of the ‘578 patent depends from claim 44, which depends from claim 43. Claim 44 reads:

> 44. The formulation of claim 43, wherein said systemically active therapeutic agent is selected from the group consisting of antihistamines, analgesics, non-steroidal anti-inflammatory agents, gastro-intestinals, anti-emetics, anti-epileptics, vasodilators, anti-tussive agents, expectorants, anti-asthmatics, hormones, diuretics, anti-hypotensives, anti-hypertensives, bronchodilators, antibiotics, antivirals, antihemorrhoidals, steroids, hypnotics, psychotropics, antidiarrheals, mucolytics, sedatives, decongestants, laxatives, vitamins, and stimulants.

Claim 47 reads:

> 47. The formulation of claim 44, wherein said agent is an opioid analgesic selected from the group consisting of hydromorphone, oxycodone, morphine, levorphanol, methadone, meperidine, heroin, dihydrocodeine, codeine, hydrocodone, tramadol, dihydromorphine, buprenorphine, mixed opiate receptor agonist-antagonists, salts, hydrates and solvents of any of the foregoing, and mixtures of any of the foregoing.

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 94.

95. Admitted.

96. Dependent claim 40 of the ‘578 patent depends from claim 37 which depends from claim 36. Claim 37 reads:

> 37. The formulation of claim 36, wherein said therapeutically active agent is selected from the group consisting of antihistamines, analgesics, non-steroidal anti-inflammatory agents, gastro-intestinals, anti-emetics, anti-epileptics, vasodilators, anti-tussive agents, expectorants, anti-asthmatics, hormones, diuretics, anti-hypotensives, anti-hypertensives, bronchodilators, antibiotics, antivirals, antihemorrhoidals, steroids, hypnotics, psychotropics,

> antidiarrheals, mucolytics, sedatives, decongestants, laxatives, vitamins, and stimulants.

Claim 40 reads:

> 40. The formulation of claim 37, wherein said active agent is an opioid analgesic selected from the group consisting of hydromorphone, oxycodone, morphine, levorphanol, methadone, meperidine, heroin, dihydrocodeine, codeine, hydrocodone, tramadol, dihydromorphine, buprenorphine, mixed opiate receptor agonist-antagonists, salts, hydrates and solvents of any of the foregoing, and mixtures of any of the foregoing.

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 96.

97. Mr. Davidson was an attorney of record in the prosecution of the '558 application and the '798 application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 97.

98. Admitted.

99. Denied.

100. Admitted.

101. Admitted.

102. Admitted.

103. Admitted.

104. Paragraph 104 misquotes "pharmaceutically acceptable salt" as "pharmaceutically salt." Paragraph 104 otherwise accurately quotes originally filed claim 53 of the '798 application.

105. Admitted.

106. Paragraph 106 misquotes "said tablet" as "said preparation." Paragraph 106 otherwise accurately quotes originally filed claim 63 of the '798 application.

107. Admitted.

108. Admitted.

109. The element "spheroid substrates" appears in original claims 46 and 54 of the '798 application. The element "tramadol hydrochloride" appears in original claims 49 and 57 of the '798 application. The element "controlled release coating" appears in original claim 58 of the '798 application. The element "substrate is a tablet" appears in claims 52 and 62 of the '798 application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 109.

110. The '798 application issued as the '887 patent. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 110.

111. Denied.

112. Denied.

113. An office action dated December 16, 1994, stated: "[c]laims 1, 2, 5, 6, 8-29, 32-42, 45-52, 55-59, 61, 73 and 94-99 are rejected under judicially created policy as consisting double patenting over Oshlack et al. 5,286,493." The '558 application was filed as a continuation-in-part of U.S. Patent No. 5, 286,493. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 113.

114. 37 C.F.R. § 1.56 ("Rule 56") states: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 114.

115. 37 C.F.R. § 1.56 ("Rule 56") is titled "Duty to disclose information material to patentability." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 115.

116. The persons subject to the duty to disclose are identified in 37 C.F.R. § 1.56(a). Mr. Davidson, who was an attorney of record in the prosecution of the '798 application, was subject to that duty. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 116.

117. MPEP § 2001.06(b) (2007) states: "The individuals covered by 37 CFR 1.56 have a duty to bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications which are 'material to patentability' of the application in question." Some Federal Circuit decisions have held that, under specific facts, the failure to disclose another patent application to the Patent and Trademark Office was a material omission. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 117.

118. Purdue and Napp deny. Biovail and OMI deny on information and belief.

119. The prosecution history of the '887 patent does not reflect that the copending '558 application was disclosed during prosecution. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 119.

120. Mr. Davidson was generally aware of the requirements of 37 C.F.R. § 1.56. Plaintiffs are without information and belief as to what the corporate entity "Euro-Celtique" knew. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 120.

121. On information and belief, admitted. The file history as obtained from the PTO was incomplete. Once the full file history is assembled, Plaintiffs reserve the right to amend their answer to paragraph 121.

122. Purdue and Napp deny. Biovail and OMI deny on information and belief.

123. Purdue and Napp deny. Biovail and OMI deny on information and belief.

124. An office action dated December 16, 1994, stated: "Claims 1, 2, 5, 6, 8-29, 32-42, 45-52, 55-59, 61, 73 and 94-99 are rejected under judicially created policy as consisting double patenting over Oshlack et al. 5,286,493." The office action further stated: "Claims 1, 2, 5, 6, 8-29, 32-42, 45-52, 55-59, 61, 73, and 94-99 are rejected under 35 U.S.C. § 103 as being unpatentable over Fawzi et al. 5,068,11 [sic] or Ghebre-Sellassie et al. 4,00,645 or Edgren et al. 5,024,842 or Wong et al. 5,019,397." The '558 application, assigned to Euro-Celtique, was filed as a continuation-in-part of U.S. Patent No. 5,286,493, also assigned to Euro-Celtique. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 124.

125. The December 16, 1994 office action was signed by Peter Kulkosky. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 125.

126. The '558 application was filed on July 27, 1993, and issued on December 3, 1996. The '798 application was filed on July 10, 1996. Mr. Davidson was an attorney of record for the '798 application. Euro-Celtique is the assignee of the '798 application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 126.

127. Denied.

128. Admitted.

129. Originally filed claim 58 depended from claim 55 which depended from claim 52 of the '558 application. Originally filed claim 55 read:

> 55. The formulation of claim 52, wherein said systematically active therapeutic agent is selected from the group consisting of antihistamines, analgesics, non-steroidal anti-inflammatory agents, gastro-intestinals, anti-emetics, anti-epileptics, vasodilators, anti-tussive agents, expectorants, anti-asthmatics, hormones, diuretics, anti-hypotensives, anti-hypertensives, bronchodilators, antibiotics, antivirals, antihemorrhoidals, steroids, hypnotics, psychotropics, antidiarrheals, mucolytics, sedatives, decongestants, laxatives, vitamins, and stimulants.

Originally filed claim 58 read:

> 58. The formulation of claim 55, wherein said agent is an opioid analgesic selected from the group consisting of hydromorphone, oxycodone, morphine, levorphanol, methadone, meperidine, heroin, dihydrocodeine, codeine, hydrocodone, tramadol, dihydromorphine, buprenorphine, mixed opiate receptor agonist-antagonists, salts, hydrates and solvents of any of the foregoing, and mixtures of any of the foregoing.

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 129.

130. Paragraph 130 misquotes "(pH between 1.6 and 7.2)" as "(pH between 6 and 7.2)." Paragraph 130 otherwise accurately quotes originally filed claim 42 of the '558 application.

131. Originally filed claim 48 depended from claim 45 which depended from claim 42 of the '558 application. Originally filed claim 45 read:

> 45. The formulation of claim 42, wherein said therapeutically active agent is selected from the group consisting of antihistamines, analgesics, non-steroidal anti-inflammatory agents, gastro-intestinals, anti-emetics, anti-epileptics, vasodilators, anti-tussive agents, expectorants, anti-asthmatics, hormones, diuretics, anti-hypotensives, anti-hypertensives, bronchodilators, antibiotics, antivirals, antihemorrhoidals, steroids, hypnotics, psychotropics, antidiarrheals, mucolytics, sedatives, decongestants, laxatives, vitamins, and stimulants.

Originally filed claim 48 read:

> 48. The formulation of claim 48, wherein said active agent is an opioid analgesic selected from the group consisting of hydromorphone, oxycodone, morphine, levorphanol, methadone, meperidine, heroin, dihydrocodeine, codeine, hydrocodone, tramadol, dihydromorphine, buprenorphine, mixed opiate receptor agonist-antagonists, salts, hydrates and solvents of any of the foregoing, and mixtures of any of the foregoing.

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 131.

132. Some Federal Circuit decisions have held that, under specific facts, the failure to disclose another patent application to the Patent and Trademark Office was a material omission. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 132.

133. Purdue and Napp deny. Biovail and OMI deny on information and belief.

134. The prosecution history does not reflect that rejections made in the '558 application were disclosed during prosecution of the '798 application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 134.

135. Purdue and Napp deny. Biovail and OMI deny on information and belief.

136. Denied.

137. Denied.

138. The '578 patent specification contains the statement: "The present invention is further related to a method of treating a patient with an oral solid dosage form described above. In this method, present invention further comprises administering the oral solid dosage form comprising the cured, coated substrate to the patient to thereby obtain the desired therapeutic effect for about 12 to about 24 hours or more. In especially preferred embodiments, the oral solid dosage forms of the present invention provide a desired therapeutic effect for about 24 hours." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 138.

139. The specification of the '578 patent includes the use of the word "substrate." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 139.

140. The '578 patent specification states: "The aqueous dispersions of hydrophobic acrylic polymers used as coatings in the present invention may be used to coat substrates such as tablets, spheroids (or beads), microspheres, seeds, pellets, ion-exchange resin

beads, and other multi-particulate systems in order to obtain a desired controlled release of the active agent." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 140.

141. The '578 patent discloses fifteen (15) classes of active agents, one of which is "systemically active therapeutic agents," twenty-eight (28) classes of systemically active therapeutic agents, one of which is "opioids," and fourteen (14) different opioids, one of which is tramadol. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 141.

142. The '578 patent specification states: "A further object of the present invention is to provide a controlled release formulation wherein the controlled release is caused by a coating on the formulation of an aqueous dispersion of a hydrophobic polymer such as an acrylic polymer which coating provides a stable dissolution of an active agent contained in the formulation, despite exposure to accelerated storage conditions such that the dissolution would be deemed acceptable by a governmental regulatory agency such as the U.S. FDA for purposes of according expiration dating." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 142.

143. The '578 patent specification states: "It is therefore an object of the present invention to provide a controlled release formulation of a substrate comprising an active agent, e.g. a therapeutically active agent, a disinfecting agent, a cleansing agent, a sanitizing agent and a fertilizing agent, coated with an aqueous dispersion of a hydrophobic acrylic polymer such that there is a stable dissolution or other release profile of the active agent when placed in an environment of use, despite exposure to a variety of storage conditions, including accelerated storage conditions." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 143.

144. The dissolution ranges "when measured by the USP Paddle or Basket Method at 100 rpm at 900 ml aqueous buffer (pH between 6 and 7.2) at 37°C" set forth in claim 36 and 43 of the '578 patent are:

Time (hr)	**Claim 36 % Released (by weight)**	**Claim 43 % Released (by weight)**
1	"about 0% to about 42.5%"	"about 0% to about 42.5%"
2	"about 25% to about 55%"	"about 5% to about 60%"
4	"about 45% to about 75%"	"about 15% to about 75%"
6	"greater than about 55%"	--
8		"about 20% to about 90%"

The dissolution ranges "when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm" set forth in claims 1, 3, 4, 13, 15, 17, and 19 of the '887 patent are:

Time (hr)	**Claim 1 % Released**	**Claim 3 % Released**	**Claim 4 % Released**	**Claim 13 % Released**	**Claim 15 % Released**	**Claim 17 % Released**	**Claim 19 % Released**
1	0-50	0-50	0-30	0-50	0-50	15-25	0-50
2	0-75	0-75	0-45	0-75	0-75	25-35	0-75
4	3-95	10-95	3-55	3-95	10-95	30-45	3-95
8	10-100	35-100	10-65	10-100	35-100	40-60	10-100
12	20-100	55-100	20-75	20-100	55-100	55-70	20-100
16	30-100	70-100	30-88	30-100	70-100	60-75	30-100
24	50-100	>90	50-100	50-100	>90	--	50-100

Time (hr)	Claim 1 % Released	Claim 3 % Released	Claim 4 % Released	Claim 13 % Released	Claim 15 % Released	Claim 17 % Released	Claim 19 % Released
36	>80	--	>80	>80	--	--	>80

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 144.

145. Admitted.

146. Admitted.

147. The '578 patent was filed on July 27, 1993. The German '525 priority application was filed on May 10, 1993. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 147.

148. Denied.

149. In the German '525 priority application, in vitro dissolution rate ranges stated for the controlled release preparations, when measured by USP Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm, are between 5 and 50% (by weight) tramadol released after 1 hour, between 10 and 75% (by weight) tramadol released after 2 hours, between 20 and 95% (by weight) tramadol released after 4 hours, between 40 and 100% (by weight) tramadol released after 8 hours, more than 50% (by weight) tramadol released after 12 hours, more than 70% (by weight) tramadol released after 18 hours and more than 80% (by weight) tramadol released after 24 hours. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 149.

150. The dissolution ranges "when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm" set forth in claims 1, 3, 4, 13, 15, 17, and 19 of the '887 patent are:

Time (hr)	Claim 1 % Released	Claim 3 % Released	Claim 4 % Released	Claim 13 % Released	Claim 15 % Released	Claim 17 % Released	Claim 19 % Released
1	0-50	0-50	0-30	0-50	0-50	15-25	0-50
2	0-75	0-75	0-45	0-75	0-75	25-35	0-75
4	3-95	10-95	3-55	3-95	10-95	30-45	3-95
8	10-100	35-100	10-65	10-100	35-100	40-60	10-100
12	20-100	55-100	20-75	20-100	55-100	55-70	20-100
16	30-100	70-100	30-88	30-100	70-100	60-75	30-100
24	50-100	>90	50-100	50-100	>90	--	50-100
36	>80	--	>80	>80	--	--	>80

Claims 5-6, 16, 18, 20, and 27 depend from claim 1 and do not further limit the in vitro dissolution parameters of claim 1. Claims 22-26 and 31-32 depend from claim 19 and do not further limit the in vitro dissolution parameters of claim 19. Claim 29 depends from claim 13 and does not further limit the in vitro dissolution parameters of claim 13. Claims 5-6, 16, 18, 20, and 27 depend from claim 1 and do not further limit the in vitro dissolution parameters of claim 1. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 150.

151. MPEP § 2001.04 (2007) is titled "Information Under 37 CFR 1.56(a)" and quotes that section in its entirety. Some Federal Circuit decisions have held that, under specific facts, the failure to disclose a prior art patent to the Patent and Trademark Office was a material omission. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 151.

152. Purdue and Napp deny. Biovail and OMI deny on information and belief.

153. Mr. Davidson was generally aware of the requirements of 37 C.F.R. § 1.56. Plaintiffs are without information and belief as to what the corporate entity "Euro-Celtique" knew. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 153.

154. The prosecution history of the U.S. Application Serial No. 09/800,204 ("the '204 application"), filed March 6, 2001, reflects that the '578 patent was disclosed. The '204 application is a continuation of the '798 application. The prosecution history of the '798 application does not reflect that the '578 patent was disclosed. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 154.

155. Purdue and Napp deny. Biovail and OMI deny on information and belief.

156. Admitted.

157. Admitted.

158. The abstract of U.S. Patent No. 5,478,577 ("the '577 patent") states:

> Patients are treated with 24-hour oral sustained release opioid formulations which upon administration quickly release an effective portion of the opioid contained therein such that there is an initially more rapid opioid release so that the minimum effective analgesic concentration of the opioid can be more quickly achieved. In the method, the formulations are designed to provide a relatively large peak to trough concentration of the opioid, rather than a flattened serum concentration curve.

The specification further states that "[i]n certain preferred embodiments of the present invention, the sustained-release opioid dosage forms comprise a plurality of substrates comprising the active ingredient, which substrates are coated with a sustained-release coating." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 158.

159. The '577 patent states that seventy-two (72) possible opioids and "salts thereof" "may be used in the present invention." One of the listed opioids is tramadol. The patent also lists seven opioids as the "preferred embodiments." Tramadol is not disclosed as a

"preferred embodiment." Tramadol is not listed in any claim of the '577 patent. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 159.

160. Admitted.

161. Admitted.

162. Mr. Davidson was an attorney of record for U.S. Application Serial No. 08/156,468 ("the '468 application"). Except as expressly admitted, Plaintiffs deny the averments of Paragraph 162.

163. The face of the '577 patent lists William E. Benston, Jr. as the assistant examiner. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 163.

164. Denied.

165. Denied.

166. The '577 patent abstract states:

> Patients are treated with 24-hour oral sustained release opioid formulations which upon administration quickly release an effective portion of the opioid contained therein such that there is an initially more rapid opioid release so that the minimum effective analgesic concentration of the opioid can be more quickly achieved. In the method, the formulations are designed to provide a relatively large peak to trough concentration of the opioid, rather than a flattened serum concentration curve.

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 166.

167. The '577 specification states that "[i]n certain preferred embodiments of the present invention, the sustained-release opioid dosage forms comprise a plurality of substrates comprising the active ingredient, which substrates are coated with a sustained-release coating." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 167.

168. The '577 specification states that "Where a plurality of the sustained release substrates comprising an effective unit dose of the opioid (e.g., multiparticulate systems

including pellets, spheres, beads and the like) are incorporated into a hard gelatin capsule, the immediate release portion of the opioid dose may be incorporated into the gelatin capsule via inclusion of the sufficient amount of immediate release opioid as a powder or granulate within the capsule." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 168.

169. The '577 patent lists seventy-two (72) possible opioids and "salts thereof" that "may be used in the present invention." One of the listed opioids is tramadol. The patent also lists seven opioids as the "preferred embodiments." Tramadol is not listed as a "preferred embodiment." Tramadol is not listed in any claim of the '577 patent. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 169.

170. The '577 specification states:

> In certain preferred embodiments of the present invention, an effective amount of opioid in immediate release form is included in the 24 hour sustained release unit dose opioid formulation to be administered. The immediate release form of the opioid is included in an amount which is effective to shorten the time to maximum concentration of the opioid in the blood (e.g., plasma), such that the T_{max} is shortened to a time of, e.g., from about 2 to about 4 hours. This causes the blood concentration curve to have an early peak rather than the substantially flattened curves currently recommended by those skilled in the art. It has been discovered that by including such an effective amount of immediate release opioid in the unit dose, the experience of relatively higher levels of pain in patients is significantly reduced. In such embodiments, an effective amount of the opioid in immediate release form may be coated onto the substrates of the present invention. For example, where the extended release opioid from the formulation is due to a controlled release coating, the immediate release layer would be overcoated on top of the controlled release coating.

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 170.

171. The '577 specification states that "[i]n certain preferred embodiments of the present invention, the hydrophobic polymer comprising the sustained-release coating is a pharmaceutically acceptable acrylic polymer" and "[i]n other preferred embodiments, the

hydrophobic polymer which may be used for coating the substrates of the present invention is a hydrophobic cellulosic material." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 171.

172. The dissolution ranges using "U.S.P. Apparatus II (Paddle Method) [in] 700 ml of simulated gastric fluid (without enzymes) for the first hour at 100 rpm and 37°C., and then placed into 900 ml of simulated gastric fluid (without enzymes) after the first hour" to measure "percent Morphine Sulfate Dissolved" are:

Time	Example 1	Example 2	Example 3
1	11.9%	10.2%	11.7%
2	15.4%	11.3%	12.1%
4	28.1%	12.8%	22.0%
8	58.3%	16.4%	45.3%
12	79.2%	29.6%	63.7%
18	92.0%	58.1%	81.8%
24	96.6%	73.2%	92.5%

The dissolution ranges "when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm" set forth in claims 1, 3, 4, 13, 15, 17, and 19 of the '887 patent are:

Time (hr)	Claim 1 % Released	Claim 3 % Released	Claim 4 % Released	Claim 13 % Released	Claim 15 % Released	Claim 17 % Released	Claim 19 % Released
1	0-50	0-50	0-30	0-50	0-50	15-25	0-50
2	0-75	0-75	0-45	0-75	0-75	25-35	0-75
4	3-95	10-95	3-55	3-95	10-95	30-45	3-95
8	10-100	35-100	10-65	10-100	35-100	40-60	10-100
12	20-100	55-100	20-75	20-100	55-100	55-70	20-100

Time (hr)	Claim 1 % Released	Claim 3 % Released	Claim 4 % Released	Claim 13 % Released	Claim 15 % Released	Claim 17 % Released	Claim 19 % Released
16	30-100	70-100	30-88	30-100	70-100	60-75	30-100
24	50-100	>90	50-100	50-100	>90	--	50-100
36	>80	--	>80	>80	--	--	>80

173. Admitted.

174. Admitted.

175. The '577 application was filed on November 23, 1993. The German '525 priority application was filed on May 10, 1993. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 175.

176. Denied.

177. In the German '525 priority application, in vitro dissolution rate ranges stated for the controlled release preparation, when measured by USP Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm, are between 5 and 50% (by weight) tramadol released after 1 hour, between 10 and 75% (by weight) tramadol released after 2 hours, between 20 and 95% (by weight) tramadol released after 4 hours, between 40 and 100% (by weight) tramadol released after 8 hours, more than 50% (by weight) tramadol released after 12 hours, more than 70% (by weight) tramadol released after 18 hours and more than 80% (by weight) tramadol released after 24 hours. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 177.

178. The dissolution ranges "when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 nm" set forth in claims 1, 3, 4, 13, 15, 17, and 19 of the '887 patent are:

Time (hr)	Claim 1 % Released	Claim 3 % Released	Claim 4 % Released	Claim 13 % Released	Claim 15 % Released	Claim 17 % Released	Claim 19 % Released
1	0-50	0-50	0-30	0-50	0-50	15-25	0-50
2	0-75	0-75	0-45	0-75	0-75	25-35	0-75
4	3-95	10-95	3-55	3-95	10-95	30-45	3-95
8	10-100	35-100	10-65	10-100	35-100	40-60	10-100
12	20-100	55-100	20-75	20-100	55-100	55-70	20-100
16	30-100	70-100	30-88	30-100	70-100	60-75	30-100
24	50-100	>90	50-100	50-100	>90	--	50-100
36	>80	--	>80	>80	--	--	>80

Claims 5-6, 16, 18, 20, and 27 depend from claim 1 and do not further limit the in vitro dissolution parameters of claim 1. Claims 22-26 and 31-32 depend from claim 19 and do not further limit the in vitro dissolution parameters of claim 19. Claim 29 depends from claim 13 and does not further limit the in vitro dissolution parameters of claim 13. Claims 5-6, 16, 18, 20, and 27 depend from claim 1 and do not further limit the in vitro dissolution parameters of claim 1. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 178.

179. MPEP § 2001.04 (2007) is titled "Information Under 37 CFR 1.56(a)" and quotes that section in its entirety. Some Federal Circuit decisions have held that, under specific facts, the failure to disclose a prior art patent to the Patent and Trademark Office was a material omission. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 179.

180. Purdue and Napp deny. Biovail and OMI deny on information and belief.

181. Mr. Davidson was generally aware of the requirements of 37 C.F.R. § 1.56. Plaintiffs are without information and belief as to what the corporate entity "Euro-Celtique" knew. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 181.

182. The prosecution history of the U.S. Application Serial No. 09/800,204 ("the '204 application"), filed March 6, 2001, reflects that the '577 patent was disclosed. The '204 application is a continuation of the '798 application. The prosecution history of the '798 application does not reflect that the '577 patent was disclosed. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 182.

183. Purdue and Napp deny. Biovail and OMI deny on information and belief.

184. MPEP § 2001.06(c) (2007) states: "Where the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office." Some Federal Circuit decisions have held that, under specific facts, the failure to disclose litigation related to a patent application to the Patent and Trademark Office was a material omission. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 184.

185. The '577 patent was originally asserted in Purdue Pharma L.P. v. F.H. Faulding, No. 96-cv-427 (April 23, 1999 D. Del.) ("the Faulding litigation"). Purdue Pharma L.P. dropped all claims based on the '577 patent in favor of asserting U.S. Patent No. 5,672,360. The opinion in the Faulding decision does not reference the '577 patent. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 185.

186. The ‘577 patent abstract states:

> Patients are treated with 24-hour oral sustained release opioid formulations which upon administration quickly release an effective portion of the opioid contained therein such that there is an initially more rapid opioid release so that the minimum effective analgesic concentration of the opioid can be more quickly achieved. In the method, the formulations are designed to provide a relatively large peak to trough concentration of the opioid, rather than a flattened serum concentration curve.

The ‘577 patent discloses seventy-two (72) possible opioids and “salts thereof” that “may be used in the present invention.” One of the listed opioids is tramadol. The patent also discloses seven opioids as the “preferred embodiments.” Tramadol is not disclosed as a “preferred embodiment.” Tramadol is not listed in any claim of the ‘577 patent. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 186.

187. The ‘887 patent discloses and claims controlled release preparations for oral administration containing tramadol or a pharmaceutically acceptable salt thereof, as the active ingredient. The patent specification states: “It is an object of the present invention to provide an oral controlled release tramadol preparation suitable for at least twelve-hourly (e.g. up to twenty-four hourly) administration for the treatment of pain.” Except as expressly admitted, Plaintiffs deny the averments of Paragraph 187.

188. Purdue and Napp deny. Biovail and OMI deny on information and belief.

189. Purdue and Napp deny. Biovail and OMI deny on information and belief.

190. In response to an Information Disclosure Statement filed on October 9, 1997, the Examiner issued an Office Action on October 27, 1998 requesting “a brief summary of each of the 129 references listed, including their relevance to the pending claims.” Except as expressly admitted, Plaintiffs deny the averments of Paragraph 190.

191. An Office Action was sent on October 27, 1998. Paragraph 191 accurately quotes a portion of that Office Action. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 191.

192. Purdue and Napp deny. Biovail and OMI deny on information and belief.

193. Denied.

194. Denied.

195. The Merck reference states: "The invention relates to a novel method and compositions for release of drugs through a rate limiting barrier by coating a formulation with polyvinyl alcohol, which serves as a membrane for said drugs or acts as a barrier film which will selectively permit passage of the desired species." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 195.

196. The Merck reference states: "Generally, the amount of polyvinyl alcohol film coating for the entire drug delivery device (tablet, capsule, suppository & etc.) ranges from 1% to 15% by weight of the entire drug delivery device, preferably from 3% to 10%." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 196.

197. The Merck reference discloses eleven (11) classes of active agents including "Non-Steroidal anti-inflammatory agents." Tramadol is one of 61 non-steroidal anti-inflammatory agents and one of twelve (12) preferred non-steroidal anti-inflammatory agents described in the Merck reference. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 197.

198. An Experimental Report of Dr. Helmut Momberger was submitted by Asta Medica Limited in the United Kingdom litigation captioned Napp Pharmaceutical Group

Limited v. Asta Medica Group Limited. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 198.

199. In the March 1, 1999 Information Disclosure Statement Concerning Related Foreign Litigation submitted to the Patent Office, in addition to the paragraphs quoted by Defendants in Paragraph 199, Applicants stated: "In general, the experimental report does not directly reproduce any of the Examples in the Merck reference. The amounts of microcyrstalline cellulose, tramadol hydrochloride and magnesium stearate employed approximate Example 1 if 200 mg tramadol is used in place of 250 mg of L-dopa." Applicants also reproduced Example 1 of the Merck reference in its entirety. The Merck reference discloses the loading as "the dried polymer weight of the total tablet weight." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 199.

200. Paragraph 200 reproduces a portion of Table 4.1 entitled Rate of tramadol release from PVA film-coated tablets from the Experimental Report of Dr. Momberger. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 200.

201. The Experimental Report of Dr. Momberger included a Summary of Results graph of the Rate of Tramadol Release from PVA Film-coated Tablets. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 201.

202. The dissolution ranges "when measured using the PH. Eur. Paddle Method at 100rpm in 900ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm" set forth in claim 1 of EP 0 624 366 are:

Time (hr)	**% Released**
1	5-50
2	10-75

Time (hr)	% Released
4	20-95
8	40-100
12	>50
18	>70
24	>80

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 202.

203. In the Experimental Report of Dr. Momberger, the direct compression tablet with 9.0% PVA has an average in vitro dissolution rate after 1 hr of 26%, after 2 hrs of 63% and after 4 hrs of 95%. No average in vitro dissolution rates were reported for the 8 hrs, 12 hrs, 18 hrs or 24 hrs time points. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 203.

204. In the Experimental Report of Dr. Momberger, the results for the precompression tablet with 10.0% PVA has an average in vitro dissolution rate after 1 hr of 17%, after 2 hrs of 42%, after 4 hrs of 80%, after 8 hrs of 102%, after 12 hrs of 104% and after 24 hrs of 101%. No average in vitro dissolution rate was reported for the 18 hrs time point. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 204.

205. In the Experimental Report of Dr. Momberger, the direct compression tablet with 13.0% PVA has an average in vitro dissolution rate after 1 hr of 6%, after 2 hrs of 24%, after 4 hrs of 63%, after 8 hrs of 100%, after 12 hrs of 103% and after 24 hrs of 102%. No average in vitro dissolution rate was reported for the 18 hrs time point. The results for the precompression tablet with 15.0% PVA has an average in vitro dissolution rate after 1 hr of 3%, after 2 hrs of 17%, after 4 hrs of 47%, after 8 hrs of 90%, after 12 hrs of 100% and after 24 hrs of

101%. No average in vitro dissolution rate was reported for the 18 hrs time point. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 205.

206. Denied.

207. Denied.

208. In the March 1, 1999 Information Disclosure Statement Concerning Related Foreign Litigation submitted to the Patent Office, the Applicants submitted a Report of Repeat Experiment carried out at the request of the plaintiff (NAPP Pharmaceutical Group, Limited). The Report of Repeat Experiment states: "Repetition of the teaching of European Patent Application 0 147 780 ('Merck')." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 208.

209. The '798 application was filed on July 10, 1996 as a divisional application of the '129 application. Euro-Celtique was named as the assignee for the '798 application. Since May 4, 2007, Purdue Pharma Products L.P. and Napp Pharmaceutical Group Ltd. have been the assignees of the '887 patent and the '430 patent. Napp Pharmaceutical Group Ltd. was the Plaintiff in the United Kingdom litigation captioned Napp Pharmaceutical Group Limited v. Asta Medica Group Limited. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 209.

210. The testing reported in the Report of Repeat Experiment was carried out at Temmler Pharma GmbH. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 210.

211. In the March 1, 1999 Information Disclosure Statement Concerning Related Foreign Litigation submitted to the Patent and Trademark Office, the Applicants stated:

> It is respectfully submitted that the Report of Repeat Experiment adds nothing to the Momberger report. The example made with a

> 5% polyvinyl alcohol coating falls outside of the lower limits of the claimed dissolution ranges of the EP patent (and of the pending claims as well).

The IDS submitted the "Report of Repeat Experiment" to the patent examiner. The IDS was signed by Mr. Davidson, as attorney for Applicants and Euro-Celtique. The IDS also submitted the Report of Repeat Experiment. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 211.

212. Denied.

213. The Report of Repeat Experiment provides the rate of tramadol release from PVA film-coated tablets with "PVA expressed as a percentage (w/w) of dried PVA to the weight of the film-coated tablets obtained)" of 5%, 7.5%, 10%, 12.5% and 15%. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 213.

214. Paragraph 214 reproduces a portion of Table 4.1 entitled Rate of tramadol release from PVA film-coated tablets from the Report of Repeat Experiment. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 214.

215. The Report of Repeat Experiment included Summary Results in a graph entitled "Rate of Tramadol Release from PVA Film-coated Tablets." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 215.

216. In the Report of Repeat Experiment, the reported mean rate of tramadol release of the PVA film-coated tablets, by percent PVA, are:

TIME	**7.5% PVA**	**10% PVA**	**12.5% PVA**	**15% PVA**
1	6%	17.8%	7.8%	3.2%
2	58%	41.9%	27.2%	17.1%
4	92%	80.0%	64.2%	48%

TIME	7.5% PVA	10% PVA	12.5% PVA	15% PVA
8	100%	97.5%	97.4%	89.7%
12	101.3%	100.9%	101.6%	98.7%
18	101.6%	100.6%	101.3%	100.1%
24	101.5%	100.5%	101.7%	100.9%

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 216.

217. In the Report of Repeat Experiment, the reported mean rate of tramadol release of the PVA film-coated tablets with 7.5% PVA are:

TIME	7.5% PVA
1	6%
2	58%
4	92%
8	100%
12	101.3%
18	101.6%
24	101.5%

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 217.

218. In the Report of Repeat Experiment, the reported mean rate of tramadol release of the PVA film-coated tablets with 10% PVA and 12.5% PVA are:

TIME	10% PVA	12.5% PVA
1	17.8%	7.8%
2	41.9%	27.2%

TIME	10% PVA	12.5% PVA
4	80.0%	64.2%
8	97.5%	97.4%
12	100.9%	101.6%
18	100.6%	101.3%
24	100.5%	101.7%

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 218.

219. In the Report of Repeat Experiment, the reported mean rate of tramadol release of the PVA film-coated tablets with 15% PVA are:

TIME	15% PVA
1	3.2%
2	17.1%
4	48.0%
8	89.7%
12	98.7%
18	100.1%
24	100.9%

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 219.

220. Denied.

221. Denied.

222. Denied.

223. The Report of Repeat Experiment provides the Rate of tramadol release from PVA film-coated tablets with "PVA expressed as a percentage (w/w) of dried PVA to the

weight of the film-coated tablets obtained)" of 5%, 7.5%, 10%, 12.5% and 15%. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 223.

224. The Report of Repeat Experiment provides the Rate of tramadol release from PVA film-coated tablets with "PVA expressed as a percentage (w/w) of dried PVA to the weight of the film-coated tablets obtained)" of 5%, 7.5%, 10%, 12.5% and 15%. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 224.

225. In the March 1, 1999 Information Disclosure Statement Concerning Related Foreign Litigation submitted to the Patent Office, the Applicants described the affidavit of Alexander Florence that was submitted in the UK proceedings as follows:

> Attached hereto as Exhibit E is a copy of the Third Affidavit of Alexander Florence submitted by Napp in the U.K. litigation which addresses the experiments undertaken by defendant Asta in relation to the Merck patent application (EP 147 780).

Paragraph 225 correctly quotes an excerpt from the IDS that followed, which provided the Florence Affidavit to the Examiner. That excerpt concludes "See Exhibit E," directing the Examiner to the full report. Mr. Davidson signed the IDS as attorney for Applicants and for assignee, Euro-Celtique. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 225.

226. Denied.

227. In the March 10, 2000 Information Disclosure Statement Concerning Related Foreign Litigation, the Applicants updated the Examiner on the Opposition To European Patent No. 624 366 and the Napp Pharmaceutical Group Limited v. Asta Medica Group Limited litigation in the United Kingdom. The Applicants repeated their statements in the March 1, 1999 Information Disclosure Statement Concerning Related Foreign Litigation regarding the Experimental Report of Dr. Momberger, the Report of Repeat Experiment, the Malkowska

Declaration, the Third Affidavit of Alexander Florence, the expert reports submitted by defendant Asta and a copy of Plaintiff Napp's February 26, 1999 letter to the European Patent Office (EPO). Except as expressly admitted, Plaintiffs deny the averments of Paragraph 227.

228. Denied.

229. In the March 10, 2000 Information Disclosure Statement Concerning Related Foreign Litigation, the Applicants submitted further information relating to proceedings in the EPO including "additional submissions to the EPO relating to novelty and lack of inventiveness (corresponding to anticipation and obviousness)." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 229.

230. In the March 10, 2000 Information Disclosure Statement Concerning Related Foreign Litigation, the Applicants stated:

> By repeating the former experiment based on Example 1 of EP 147 780 (Merck), the third Malkowska Declaration once again concludes that the release rates of tramadol in a tablet coated with polyvinyl acetate [sic] (PVA) are outside the rates claimed in the European paten in suit (EP 0 624 366), and that no real control of the release of tramadol is demonstrated by the Merck reference. The first and third Malkowska Declarations state that Example 1 of the Merck reference was not directly reproduced, either in the first or repeat experiment.

The IDS was signed by Mr. Davidson as attorney for Applicants and for assignee, Euro-Celtique. The IDS also submitted the referenced Malkowska Declarations to the patent examiner. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 230.

231. In the March 10, 2000 Information Disclosure Statement Concerning Related Foreign Litigation, the Applicants submitted the Test Report of Dr. W. Posch, Control Manager of Opposer Lannacher. The Applicants stated: "Referring to Exhibit L, tablets were prepared and coated with PVA allegedly according to Example 1 of the Merck reference." The IDS was signed by Mr. Davidson as attorney for Applicants and for assignee, Euro-Celtique.

The IDS also submitted the Test Report of Dr. W. Posch to the patent examiner. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 231.

232. The Test Report of Dr. W. Posch included two graphs. One is entitled "Tramadol ret. 250 mg Filmtablettern mit 5,2% PVA" and the second is entitled "Tramadol ret. 250 mg Filmblettern mit 9,0% PVA." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 232.

233. In the March 10, 2000 Information Disclosure Statement Concerning Related Foreign Litigation, the Applicants stated:

> Referring to Exhibit L, tablets were prepared and coated with PVA allegedly according to Example 1 of the Merck reference. In this Test Report, Dr. Posch states that the release of tramadol HCl from the film tablets he prepared (allegedly coated with 5.2% and 9.0% PVA, respectively) corresponds to that defined in claim 1 of Applicant's corresponding EP 0 624 366 patent.
>
> However, the Patentee's expert, Professor Alexander Taylor Florence, has pointed out that Dr. Posch made important modifications in the experimental procedure of Example 1 of Merck, including a precompression step (all formulations) and a multi-step, prolonged coating (at least with respect to the formulations having a 9.0% PVA coating). Important deficiencies concerning testing such as that accomplished in Exhibit L are set forth in Exhibit W, the Supplemental Expert Report of Professor Florence.

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 233.

234. In the first nine pages of the March 10, 2000 Information Disclosure Statement Concerning Related Foreign Litigation, the Applicants updated the Examiner on the opposition proceedings in the EPO related to European Patent No. 0 624 366 and the United Kingdom patent infringement litigation captioned Napp Pharmaceutical Group Limited v. Asta Medica Group Limited and submitted further information to the Patent Office regarding opposition proceeding in the EPO related to European Patent No. 0 624 366. The Applicants

submitted a brief summary of Exhibits K through T of the Information Disclosure Statement. The IDS was signed by Mr. Davidson as attorney for Applicants and for assignee, Euro-Celtique. The Exhibits themselves were also submitted to the patent examiner. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 234.

235. Denied.

236. Beginning on page 10 of the March 10, 2000 Information Disclosure Statement Concerning Related Foreign Litigation, the Applicants provided the Examiner with further information relating to the United Kingdom (UK) litigation. The Applicants submitted Exhibit W, "a copy of the Supplemental Expert Report of Professor Florence (submitted by Napp Pharmaceutical Group Limited, an associated company to Euro-Celtique, S.A., the assignee of EP 0624 366)." The Applicants also submitted a copy of Professor Florence's Report of November 25, 1998 as Exhibit X. The Applicants stated:

> In his Supplemental Report, Professor Florence discusses (a) further experiments conducted under his direction at the London School of Pharmacy on behalf of Napp (the "Construction Experiments"); (b) experiments conducted by Napp relating to the Merck patent (wherein a "matrix" product using polyvinyl alcohol (PVA) was prepared); (c) experiments conducted by Asta relating to a pre-compressed tablet coated with a mixture containing, inter alia, PVA; (d) a repeat of Napp's Merck coated tablet experiment (without precompression), in which the results differed from those in Napp's first experiment, and which dissolution results fell within those set out in the claims of the EP 0 624 366[3]; and (e) clarifies a statement made in his November 25, 1998 report concerning the percentage of PVA employed in Example 1 of the Merck patent.
>
> [3]Although Professor Florence states that the dissolution results fell within those set forth in the patent-in-suit, he also noted that the tableting machine was changed as compared to the machine used in the original experiment.

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 236.

237. The Applicants stated:

> In his Supplemental Report, Professor Florence discusses (a) further experiments conducted under his direction at the London School of Pharmacy on behalf of Napp (the "Construction Experiments"); (b) experiments conducted by Napp relating to the Merck patent (wherein a "matrix" product using polyvinyl alcohol (PVA) was prepared); (c) experiments conducted by Asta relating to a pre-compressed tablet coated with a mixture containing, inter alia, PVA; (d) a repeat of Napp's Merck coated tablet experiment (without precompression), in which the results differed from those in Napp's first experiment, and which dissolution results fell within those set out in the claims of the EP 0 624 366[3]; and (e) clarifies a statement made in his November 25, 1998 report concerning the percentage of PVA employed in Example 1 of the Merck patent.
>
> [3] Although Professor Florence states that the dissolution results fell within those set forth in the patent-in-suit, he also noted that the tableting machine was changed as compared to the machine used in the original experiment.

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 237.

238. In the Supplemental Expert Report of Professor Florence, Dr. Florence stated:

> 5. I have reviewed the results of the experiments as described in the Notice of Construction Experiments and the results of the repeat run carried out at the School of Pharmacy. I remain of the view that the matrix in the ASTA product affects the dissolution rate. However I note that there is a variation between the dissolution data in the two sets of experiments. While these data are consistent with my view, I accept that the data alone are insufficient to prove that my view is correct. Bearing in mind the variation it would, in my view, be necessary to carry out a number of additional runs to obtain a clear result. Unfortunately in the time available it has only been possible so far to produce a single batch of type A and B pellets on the repeat experiments.
>
> **The Merck experiments**
>
> 6. In my first report I commented upon the experiments that had been carried out by Napp relating to the Merck patent

and referred to in their first Notice of Experiments. Those experiments were of two types. The first involved attempts to repeat Example 1 (with tramadol substituted for L-dopa). Example 1 describes the preparation of a product with a coating of PVA. The second set of experiments was directed to making of a "matrix" product using PVA (the polymer recommended in the Merck patent.)

7. I also commented in outline upon the experiments that had been carried out by ASTA in which a pre-compressed tablet was coated with a mixture containing, inter alia, PVA. I was concerned that the pre-compression step (which is not described in the Merck patent) may be a significant factor in controlling the release of tramadol. (ASTA also described an experiment without pre-compression in their Notice but then decided to abandon it without offering a repeat.)

8. The experiments as described in Napp's Notice of Experiments did not involve pre-compression and did not produce a product falling within the release profile set out in the patent-in-suit. I understand that Napp carried out a repeat of its Merck coated tablet experiment (without pre-compression) in the presence of ASTA's representatives. The results achieved differed from those in the Notice in that the dissolution results fell within those set out in the claims of the Napp patent. (I understand that the type of tableting machine was changed because the apparent quality of tablets produced using the original machine was not good enough.)

9. In the light of these results it seems unlikely that the pre-compression step is essential to bring an Example 1 type product within the dissolution profile in the claims of the patent-in-suit. (The product made according to Example 1 is of course a coated product and does not contain a matrix.)

Except as expressly admitted, Plaintiffs deny the averments of Paragraph 238.

239. Denied.

240. Page 11 of the March 10, 2000 IDS states:

A Supplemental Expert's Report of John Tasker Fell, submitted by Asta and attached hereto as Exhibit Y (nonconfidential version), further comments on the results of the experiments performed

> relating to Example 1 of EP 147 780 as part of the repeat experiments and replys [sic] to "certain matters raised by Professor Florence". In his Report, Dr. Fell states that (a) Merck teaches the skilled man how to make controlled release formulations of tramadol which fall within the range of release parameters set out in Claim 1 of the EP 0 624 366 patent; (b) that there is no significant difference between using precompression versus direct compression techniques; (c) that "[c]oating over a period of days is perfectly standard for the manufacture of coated tablets" (See Exhibit Y, page 4, paragraph 10); (d) that the repeat experiments performed at Napp provided 5% PVA film-coated tablets that fall "squarely within the range of release rates set out in the [EP 0 624 366] patent"; and (e) discusses the use of ethylcellulose as a retardant material as a component of a controlled release formulation.

The IDS was signed by Mr. Davidson as attorney for Applicants and for assignee, Euro-Celtique. The IDS also submitted the Supplemental Expert's Report of John Tasker Fell to the patent examiner. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 240.

241. Paragraph 241 accurately quotes a portion of the March 10, 2000 IDS. The IDS was signed by Mr. Davidson as attorney for Applicants and for assignee, Euro-Celtique. The IDS also submitted the Supplemental Expert's Report of John Tasker Fell to the patent examiner. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 241.

242. Paragraph 242 accurately quotes a portion of the Supplemental Expert Report of John Tasker Fell. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 242.

243. Paragraph 243 accurately reproduces a graph from the Supplemental Expert Report of John Tasker Fell. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 243.

244. Denied.

245. Applicants' March 10, 2000 IDS states:

> A Supplemental Expert's Report of John Tasker Fell, submitted by Asta and attached hereto as Exhibit Y (nonconfidential version), further comments on the results of the experiments performed relating to Example 1 of EP 147 780 as part of the repeat experiments and replys [sic] to "certain matters raised by Professor Florence". In his Report, Dr. Fell states that (a) Merck teaches the skilled man how to make controlled release formulations of tramadol which fall within the range of release parameters set out in Claim 1 of the EP 0 624 366 patent; (b) that there is no significant difference between using precompression versus direct compression techniques; (c) that "[c]oating over a period of days is perfectly standard for the manufacture of coated tablets" (See Exhibit Y, page 4, paragraph 10); (d) that the repeat experiments performed at Napp provided 5% PVA film-coated tablets that fall "squarely within the range of release rates set out in the [EP 0 624 366] patent"; and (e) discusses the use of ethylcellulose as a retardant material as a component of a controlled release formulation.

The IDS was signed by Mr. Davidson as attorney for Applicants and for assignee, Euro-Celtique. The IDS also submitted the Supplemental Expert's Report of John Tasker Fell to the patent examiner. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 245.

246. Purdue and Napp deny. Biovail and OMI deny on information and belief.

247. Purdue and Napp deny. Biovail and OMI deny on information and belief.

248. Purdue and Napp deny. Biovail and OMI deny on information and belief.

249. Admitted.

250. Admitted.

251. Since May 4, 2007, Purdue Pharma Products L.P. and Napp Pharmaceutical Group Ltd. have been the assignees of U.S. Patent 7,074,430 ("the '430 patent"). Except as expressly admitted, Plaintiffs deny the averments of Paragraph 251.

252. Denied.

253. The ‘204 application was filed on March 6, 2001. Euro-Celtique is listed as the assignee. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 253.

254. Admitted.

255. Admitted.

256. Clifford M. Davidson was one of the attorneys granted a power of attorney for the ‘204 application. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 256.

257. The face of the ‘430 patent lists Samuel Barts as the primary examiner. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 257.

258. Plaintiffs repeat and incorporate their reply to Paragraphs 190 through 247.

259. An April 23, 2002 Office Action stated: “Claims 1-19 and 21-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raffa et al (Caplus 1992:120745, J. Phamocol. Exp. Ther. 1992, 260 (1), 275-85) in view of Bondi (EP 0147780).” Except as expressly admitted, Plaintiffs deny the averments of Paragraph 259.

260. The April 23, 2002 Office Action further stated: “The secondary reference of Bondi teaches a controlled release method for a variety of compounds of which Tramadol is listed as an example (see page 7 lines 31-34).” Except as expressly admitted, Plaintiffs deny the averments of Paragraph 260.

261. Applicants submitted a Response to the April 23, 2002 Office Action on October 23, 2002. The Response was signed by Robert Paradiso as attorney for Applicants and for assignee, Euro-Celtique. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 261.

262. Paragraph 262 accurately quotes a portion of the October 23, 2002 Response. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 262.

263. A Final Office Action, dated October 21, 2003, stated: "Claims 1 and 42-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raffa et al in view of Bondi." Except as expressly admitted, Plaintiffs deny the averments of Paragraph 263.

264. Applicants submitted a Response to the October 21, 2003 Office Action on April 23, 2004. The Response was signed by Robert Paradiso as attorney for Applicants and for assignee, Euro-Celtique. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 264.

265. Paragraph 265 accurately quotes a portion of the April 23, 2004 Response. The Response was signed by Robert Paradiso as attorney for Applicants and for assignee, Euro-Celtique. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 265.

266. Admitted.

267. Admitted.

268. In the March 10, 2000 Information Disclosure Statement Concerning Related Foreign Litigation, the Applicants provided the Examiner with further information relating to the United Kingdom (UK) litigation and further information relating to proceedings in the European Patent Office (EPO) including "additional submissions to the EPO relating to novelty and lack of inventiveness (corresponding to anticipation and obviousness)." The further information submitted by the Applicants included the Test Report of Dr. W. Posch, the Supplemental Expert Report of Professor Florence, and the Supplemental Expert Report of John Tasker Fell. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 268.

269. Denied.

270. Denied.

271. Denied.

272. Denied.

273. Purdue and Napp deny. Biovail and OMI deny on information and belief.

274. Purdue and Napp deny. Biovail and OMI deny on information and belief.

275. Plaintiffs repeat and incorporate their reply to Paragraphs 26 through 274.

276. Purdue and Napp deny. Biovail and OMI deny on information and belief.

277. Denied.

278. The '430 patent is a continuation of the '887 patent. Except as expressly admitted, Plaintiffs deny the averments of Paragraph 278.

AFFIRMATIVE DEFENSES

279. The '887 and '430 patents are not invalid.

280. Par has infringed and will infringe under 35 U.S.C. § 271 the claims of the '887 and '430 patents.

281. The '887 and '430 patents are not unenforceable.

WHEREFORE, Plaintiffs pray for judgment:

A. Dismissing Par's Counterclaims;

B. Adjudging that the '887 and '430 patents are valid and enforceable;

C. Adjudging that Par has infringed the '887 and '430 patents, and that the commercial sale, offer for sale, and/or manufacture of Par's Tablets would infringe, induce infringement of, and/or contribute to the infringement of the '887 and '430 patents;

D. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Par's ANDA No. 78-783 under § 505(j) of the Federal Food, Drug and Cosmetic Act

(21 U.S.C. § 355(j)) to be a date that is not earlier than the date of expiration of the '887 or '430 patents;

E. Preliminary and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc., their officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product that infringes the '887 or '430 patents;

F. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

G. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

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May 1, 2008
2312468

CERTIFICATE OF SERVICE

I, Rodger D. Smith II, hereby certify that on May 1, 2008, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to the following:

Frederick L. Cottrell, III
RICHARDS, LAYTON & FINGER

and that on May 1, 2008, I caused copies to be served upon the following in the manner indicated:

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